IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Achim Berthold
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REMARKS

In the Office Action mailed April 10, 2002, the Examiner has rejected claims 1-4 and 7 under 35 U.S.C. §102(b) as being anticipated by Kydonieus et al., U.S. Patent No. 5,580,573 and claims 1-5 and 7 under 35 U.S.C. §102(b) as being anticipated by Chien et al., U.S. Patent No. 5,023,084. Accordingly, applicant herein cancels claims 1-5 and 7 and adds new claims 8-14. Claim 8 is supported by page 9, lines 1-14 and page 10, lines 1-18, of the specification. Claim 9 corresponds to claim 2 as amended in the preliminary amendment, claim 10 to amended claim 4, and claim 11 to amended claim 3. Claims 12 and 14 are supported by page 10, lines 10 to 18, of the specification and claim 13 is supported by page 9, lines 20-22, of the specification.

Applicant respectfully traverses the rejection of claims 1-4 and 7 as being anticipated by Kydonieus et al. The Examiner states that Kydonieus et al. teach a temperature controlled polymeric device used for topical application. The Examiner does not reject claim 5 as being anticipated by Kydonieus et al. Applicant's new independent claim, claim 8, is a method claim which is based on former claim 5. Thus, the features and limitations of former claim 5 are incorporated into new claims 8-14 submitted herein, so that these claims are not anticipated by Kydonius et al. Moreover, Kydonius et al. teach a device for controlled release of biologically active substances, wherein the release is temperature activated. More specifically, Kydonius et al. discloses a device wherein the active agent release occurs upon raising the temperature of the polymeric device just above its glass

transition temperature (Tg) of the material (col. 2, lines 1-6). This, however, has nothing to do with applicant's invention according to the proposed new claims submitted herein, which claim a method of improving the cohesion of at least two polymer layers of a transdermal therapeutic system by reduction of the cold flow, which comprises laminating to layers consisting of polymers having different Tgs. Thus applicant respectfully requests this rejection be withdrawn.

Applicant respectfully traverses the rejection of claims 1-5 and 7 as being anticipated by Chien et al. The Examiner states that Chien et al. disclose a transdermal system containing a backing layer, a polymer layer and an adhesive layer. Applicant recognizes that Chien et al. discloses in Example 8 a trilayer transdermal therapeutic system wherein the layers I and III comprise the same polymer, that is, polyacrylic adhesive containing two different sexual hormones, i.e., ethinyl estradiol and norethindione, respectively, whereas layer II is a separating layer consisting of polyisobutylene and containing no active substance. The function of the separating layer is to minimize any migration and to decelerate the rate of transmission of the estrogen in the polymer layer (col. 13, lines 42-51). It can be taken from the whole disclosure of this reference that the polymers used for the manufacturing of bi- or tri-layer transdermal therapeutic systems are selected in view of the following properties: biological acceptance, capability of forming thin walls through which hormones can pass at a controlled rate (col. 10, lines 35-38) and not with regard to different glass transition temperatures, as claimed in the present invention.

Further, also the optional separating layer can be made of (any) polymeric material (col. 13, lines 14-15). This means that the layers of the transdermal therapeutic system disclosed in the above reference, even in the case of a trilayer transdermal therapeutic system, need not necessarily be made of different polymers. In the case of the trilayer TTS, the separating layer could also consist of the same polymer as the two other layers, provided measures are being taken to equip this layer with the separating properties which could, for example, be arrived at by increasing the thickness of the layer.

Therefore, applicant believes that Chien et al. fails to teach the present invention, according to which the polymers used for a transdermal therapeutic system comprising two or more layers are selected with regard to their properties as having different glass two transition temperatures. Even the Example 8 of Chien et al. does not teach the present invention, since nothing is said about the glass transition temperature of the selected polymers. Of course, it could be supposed that the glass transition temperatures of the DuroTak 80-1054 (col. 21, lines 22-23) used for layer I and that of Oppanol B 80 (col. 21, lines 35-36) used for layer II are different, but this can not be concluded from the teaching of said reference. It is respectfully submitted that at least the condition according to present claim 14 is not anticipated by said reference.

It is respectfully submitted that the application is now in condition for allowance, and such action is requested. No new matter has been added. The examiner is invited to telephone the undersigned if there are any matters which could be discussed to expedite the prosecution of the above-identified application.

Respectfully submitted,

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